

Attorney Docket No.: 330310.00101
Customer No. 27160

U.S. Patent Application No.
10/669,441

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED
FEB 08 2005
U.S. PATENT & TRADEMARK OFFICE
BY RE: Application of:

Leland SHAPIRO

: Group Art Unit: 1614

Application No.: 10/669,441

: Examiner: Not Yet Assigned

Filed: September 25, 2003

: Confirmation No.: 4274

For: INHIBITORS OF SERINE PROTEASE
ACTIVITY, METHODS AND
COMPOSITIONS FOR TREATMENT
OF NITRIC OXIDE INDUCED
CLINICAL CONDITIONS

: Atty. Dkt. No.: 330310.00101

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

February 8, 2005

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In compliance with the duty of disclosure under 37 C.F.R. §1.56 and in accordance with the practice under 37 C.F.R. §§1.97 and 1.98, the Examiner's attention is directed to the documents listed on the enclosed Forms PTO/SB/08A and PTO/SB/08B. Please note that these documents were all considered in related application 09/518,097, filed March 3, 2000; now U.S. Patent No. 6,489,308, issued December 3, 2002. For the convenience of the Examiner a partial copy of the above patent with the listed references is enclosed. The citation numbers have been marked on the patent for ease of comparison.

FORMAL MATTERS

In accordance with 37 C.F.R. § 1.97(b)(3), since a first Official Action on the merits of the subject application has not yet been issued, neither a certificate, petition nor payment of a fee is believed to be required for this Information Disclosure Statement. However, the Commissioner is hereby

Attorney Docket No.: 330310.00101
Customer No. 27160

U.S. Patent Application No.
10/669,441



authorized to charge any fee which may be required in connection with this paper to Deposit Account No. 50-1710.

CONCLUSION

It is respectfully requested that the above information be considered by the Examiner and that a copy of the enclosed Forms PTO/SB/08A and PTO/SB/08B be returned indicating that such information has been considered.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should continue to be directed to our address given below.

Respectfully submitted,


Serge Sira, PH.D.
Attorney for Applicant
Registration No. 39,445

Patent Administrator
KATTEN MUCHIN ZAVIS ROSENMAN
525 West Monroe Street, Suite 1600
Chicago, Illinois 60661-3963
(202) 625-3500

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1470, TRADESMAILED OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

1

of

17

Complete if Known

Application Number	10/669,441
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	1614
Examiner Name	Not Yet Assigned

Attorney Docket Number 330310.00101

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (If known)			
1	US- 4,021,472 A		05/1977	Fujii et al.	
2	US- 4,051,842 A		10/1977	Hazel et al.	
3	US- 4,140,122 A		02/1979	Kuhl et al.	
4	US- 4,224,342 A		09/1980	Fujii et al.	
5	US- 4,283,418 A		08/1981	Fuji et al.	
6	US- 4,310,533 A		01/1982	Uegai et al.	
7	US- 4,383,529 A		05/1983	Webster	
8	US- 4,629,567 A		12/1986	Bollen et al.	
9	US- 4,657,763 A		04/1987	Finkelstein	
10	US- 4,668,504 A		05/1987	Kahan et al.	
11	US- 4,711,848 A		12/1987	Insley et al.	
12	US- 4,713,224 A		12/1987	Tamhankar et al.	
13	US- 4,732,973 A		03/1988	Barr et al.	
14	US- 4,760,130 A		07/1988	Thompson et al.	
15	US- 4,788,603 A		11/1988	Fujimura et al.	
16	US- 4,829,052 A		05/1989	Glover et al.	
17	US- 4,839,283 A		06/1989	Kawasaki et al.	
18	US- 4,843,094 A		06/1989	Imaki et al.	
19	US- 4,889,723 A		12/1989	Kim et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (If known)				
20	WO 94/07525		04/1994			
21	WO 95/28422		10/1995			
22	WO 95/34538		12/1995			
23	WO 96/12021		04/1996			
24	WO 96/14067		05/1996			
25	WO 97/03679		02/1997			

Examiner Signature		Date Considered
--------------------	--	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449, PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

2

of

17

Complete if Known

Application Number	10/669,441
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	1614
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00101

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (<i>i</i> f known)			
26	US- 4,931,279 A		06/1990	Bawa et al.	
27	US- 4,963,654 A		10/1990	Katunuma	
28	US- 5,004,612 A		04/1991	Kim et al.	
29	US- 5,077,428 A		12/1991	Imaki et al.	
30	US- 5,110,602 A		05/1992	Kim et al.	
31	US- 5,157,019 A		10/1992	Glover et al.	
32	US- 5,166,134 A		11/1992	Lezdey et al.	
33	US- 5,175,253 A		12/1992	Fallon et al.	
34	US- 5,214,191 A		05/1993	Kirschenheuter et al	
35	US- 5,216,022 A		06/1993	Oleksyszyn et al.	
36	US- 5,240,956 A		08/1993	Kirschenheuter et al	
37	US- 5,247,084 A		09/1993	Imaki et al.	
38	US- 5,399,346 A		03/1995	Anderson et al.	
39	US- 5,416,191		05/1995	Cheronis et al.	
40	US- 5,420,110 A		05/1995	Miller et al.	
41	US- 5,432,178 A		07/1995	Nakai et al.	
42	US- 5,470,970 A		11/1995	Saege et al.	
43	US- 5,476,995 A		12/1995	Clark et al.	
44	US- 5,478,727 A		12/1995	Roizman et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (<i>i</i> f known)				
45	WO 97/09346		03/1997			
46	WO 97/09347		03/1997			
47	WO 97/10222		03/1997			
48	WO 97/10231		03/1997			
49	WO 97/21690		06/1997			
50	WO 97/24339		07/1997			

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449.PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet

3

of

17

Complete if Known

Application Number	10/669,441
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	1614
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00101

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (<i>If known</i>)			
51	US- 5,486,470 A		01/1996	Darke et al.	
52	US- 5,489,593 A		02/1996	Palmer et al.	
53	US- 5,504,094 A		04/1996	Nakane et al.	
54	US- 5,514,653 A		05/1996	Perlmutter	
55	US- 5,514,713 A		05/1996	Nakai et al.	
56	US- 5,529,920 A		06/1996	Cole et al.	
57	US- 5,532,215 A		07/1996	Lezdey et al.	
58	US- 5,565,334 A		10/1996	Kufe et al.	
59	US- 5,567,682 A		10/1996	Pert	
60	US- 5,593,858 A		01/1997	Fleer et al.	
61	US- 5,604,201 A		02/1997	Thomas et al.	
62	US- 5,610,140 A		03/1997	Goodfellow et al.	
63	US- 5,610,285 A		03/1997	Lebing et al.	
64	US- 5,614,555 A		03/1997	Nakai et al.	
65	US- 5,616,693 A		04/1997	Hwang et al.	
66	US- 5,618,792 A		04/1997	Gyorkos et al.	
67	US- 5,622,984 A		04/1997	Nakai et al.	
68	US- 5,635,593 A		06/1997	Cheronis et al.	
69	US- 5,641,670 A		06/1997	Treco et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (<i>If known</i>)				
70	WO 97/31937		09/1997			
71	WO 97/33996		09/1997			
72	WO 97/37969		10/1997			
73	WO 97/45402		12/1997			
74	WO 97/48706		12/1997			
75	WO 97/49679		12/1997			

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Complete if Known

Application Number	10/669,441
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	1614
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00101

Sheet 4 of 17

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (<i>If known</i>)			
76	US- 5,663,416 A	09/1997	Kirschenheuter et al		
77	US- 5,665,589 A	09/1997	Harris et al.		
78	US- 5,700,779 A	12/1997	Goodfellow et al.		
79	US- 5,710,026 A	01/1998	Sprecher		
80	US- 5,712,117 A	01/1998	Sprecher		
81	US- 5,747,645 A	05/1998	Sprecher		
82	US- 5,750,506 A	05/1998	Goodfellow et al.		
83	US- 5,759,548 A	06/1998	Bathurst et al.		
84	US- 5,780,009 A	07/1998	Karatzas et al.		
85	US- 5,798,442 A	08/1998	Gallant et al.		
86	US- 5,801,148 A	09/1998	Gyorkos et al.		
87	US- 5,804,594 A	09/1998	Murad		
88	US- 5,807,829 A	09/1998	Gyorkos et al.		
89	US- 5,811,241 A	09/1998	Goodfellow et al.		
90	US- 5,817,484 A	10/1998	Yu et al.		
91	US- 5,834,431 A	11/1998	Stewart et al.		
92	US- 5,843,900 A	12/1998	Cheronis et al.		
93	US- 5,849,863 A	12/1998	Stewart et al.		
94	US- 5,861,299 A	01/1999	Archibald et al.		

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (<i>if known</i>)				
95	WO 98/06417		02/1998			
96	WO 98/09206		03/1998			
97	WO 98/20034		05/1998			
98	WO 98/21186		05/1998			
99	WO 98/22098		05/1998			
100	WO 98/22619		05/1998			

Examiner Signature		Date Considered
--------------------	--	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Complete if Known**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

5

of

17

Application Number	10/669,441
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	1614
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00101

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (<i>if known</i>)			
101	US- 5,861,380 A		01/1999	Gyorkos et al.	
102	US- 5,863,899 A		01/1999	Cheronis et al.	
103	US- 5,869,455 A		02/1999	Gyorkos et al.	
104	US- 5,874,424 A		02/1999	Batchelor et al.	
105	US- 5,874,585 A		02/1999	Gyorkos et al.	
106	US- 5,891,852 A		04/1999	Gyorkos et al.	
107	US- 5,914,342 A		06/1999	Maurer et al.	
108	US- 6,127,356 A		10/2000	Crapo et al.	
109	US- 6,140,116 A		10/2000	Dinsmore et al.	
110	US- 6,235,714 B1		05/2001	Paul et al.	
111	US- 6,323,219 B1		11/2001	Costanzo	
224	US- 5,281,617 A		01/1994	Kirschenheuter et al	
225	US- 5,314,910 A		05/1994	Kirschenheuter et al	
226	US- 5,376,655 A		12/1994	Imaki et al.	
	US-				

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (<i>if known</i>)				
112	WO 98/23565		06/1998			
113	WO 98/24806		06/1998			
114	WO 98/46597		10/1998			
115	WO 98/49190		11/1998			
116	WO 98/50342		11/1998			
117	WO 98/50420		11/1998			

Examiner Signature		Date Considered
--------------------	--	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449, PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 6 of 17

Application Number	10/669,441
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	1614
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00101

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ *Number ⁴ *Kind Code ⁵ (if known)				
	118	WO 98/56821	12/1998			
	119	WO 97/41231	08/1999			
	120	WO 99/43308	09/1999			
	121	WO 00/52034	09/2000			

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.¹Applicant's unique citation designation number (optional).²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible.⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete if Known	
				Application Number	10/669,441
				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	7	of	17	Attorney Docket Number	330310.00101

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	122	Aoki H, Akaike T, Abe K, Kuroda M, Arai S, Okamura R, Negi A, Maeda H. Antiviral effect of oryzacystatin, a proteinase inhibitor in rice, against herpes simplex virus type I in vitro and in vivo. <i>Antimicrob Agents Chemother</i> Apr. 1995; 39(4):846-9.	
	123	Auerswald et al., "Recombinant leech-derived tryptase inhibitor: construction, production, protein chemical characterization and inhibition of HIV-1 replication", <i>Biol Chem Hoppe Seyler</i> , 375(10):695-703 (1994).	
	124	Avril LE, Di Martino-Ferrer M, Barin F, Gauthier F., "Interaction between a membrane-associated serine proteinase of U-937 monocytes and peptides from the V3 loop of the human immunodeficiency virus type I (HIV-1) gp120 envelope glycoprotein", <i>FEBS Lett</i> , 317(1-2):167-72 (Feb. 8, 1993).	
	125	Beal, M.F., "Mitochondria, Free Radicals, and Neurodegeneration", <i>Curr. Opin. Neurobiol.</i> , 1996, 6, 661-666.	
	126	Bjorck L, Grubb A, Kjellen L. Cystatin C, a human proteinase inhibitor, blocks replication of herpes simplex virus. <i>J Virol</i> Feb. 1990;64(2):941-3.	
	127	Carroccio A, Fontana M, Spagnuolo MI, Zuin G, Montalto G, Canani RB, Verghi F, Di Martino D, Bastoni K, Buffardi F, Guarino A., "Pancreatic dysfunction and its association with fat malabsorption in HIV infected children", <i>Gut</i> , 43(4):558-63 (Oct. 1998).	
	128	Cox et al., "Synergistic combinations and peptides in the inhibition of human immunodeficiency virus", <i>Adv Enzyme Regul</i> , 31:85-97 (1991).	
	129	Deigner, H.P. and R. Kinscherf, "Modulating Apoptosis: Current Applications and Prospects for Future Drug Development", <i>Curr Med Chem</i> 1999, 6, 399-414.	
	130	Dilanni CL, Drier, DA, Deckman IC, McCann PJ 3d, Liu F, Roizman B, Colonna RJ, Cordingley MG. Identification of the herpes simplex virus-I protease cleavage sites by direct sequence analysis of autoproteolytic cleavage products. <i>Biol Chem</i> Jan. 25, 1993;268(3):2048-51.	
	131	Dilanni CL, Stevens JT, Bolgar M, O'Boyle DR 2nd, Weinheimer SP, Colonna RJ. Identification of the serine residue at the active site of the herpes simplex virus type 1 protease. <i>J Biol Chem</i> Apr. 29, 1994;269(17):12672-6.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Complete if Known

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

8

of

17

Application Number

10/669,441

Filing Date

September 25, 2003

First Named Inventor

Leland SHAPIRO

Art Unit

1614

Examiner Name

Not Yet Assigned

Attorney Docket Number

330310.00101

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	132	Flaitz CM, Hicks MJ. "Molecular piracy: the viral link to carcinogenesis." Oral Oncol Nov. 1998;34(6):448-53.	
	133	Griffin, William C., "Calculation of HLB Values of Non-Ionic Sufactants", [H. L. B.--The Hydrophilic-Lipophilic Balance], J. Soc. Cos. Met. Chem., vol. 5, p. 249 (1954).	
	134	Holwerda BC. Herpesvirus proteases: targets for novel antiviral drugs. Antiviral Res Jun. 1997;35(1):1-21.	
	135	Inocencio et al., "Endoprotease activities other than furin and PACE4 with a role in processing of HIV-1 gp160 glycoproteins in CHO-K1 cells", J Biol Chem, 272(2):1344-8 (1997).	
	136	Jabs, Thorsten, "Reactive Oxygen Intermediates as Mediators of Programmed Cell Death in Plants and Animals", Biochem Pharmacol 1999, 57, 231-245.	
	137	Kaufmann, Scott H., Serge Desnoyers, Yvonne Ottaviano, Nancy E. Davidson, and Guy G. Poirier, "Specific Proteolytic Cleavage of Poly(ADP-ribose) Polymerase: An Early Marker of Chemotherapy-induced Apoptosis", Cancer Res 1993, 53, 3976.	
	138	Kidd, Vincent J., Proteolytic Activities That Mediate Apoptosis, Annu Rev Physiol, 1998, 60, 533.	
	139	Kido H, Niwa Y, Beppu Y, Towatari T. Cellular proteases involved in the pathogenicity of enveloped animal viruses, human immunodeficiency virus, influenza virus A and Sendai virus. Adv Enzyme Regul 1996;36:325-47.	
	140	Best, P.J.M., et al., Arterioscler Thromb Vasc Biol 1999, 19, 14.	
	141	Lomas DA, Elliott PR, Carrell RW. Commercial plasma alpha1-antitrypsin (Prolastin) contains a conformationally inactive, latent component. Eur. Respir J Mar. 1997;10(3):672-5	

Examiner Signature	Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449 PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/669,441
				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	9	of	17	Attorney Docket Number	330310.00101

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	142	Meylan et al., "HIV infectivity is not augmented by treatment with trypsin, Factor Xa or human mast-cell tryptase", AIDS, 6(1):128-30 (1992).	
	143	Miranda et al., "Isolation of the human PC6 gene encoding the putative host protease for HIV-1 gp160 processing in CD4+ T lymphocytes", Proc Natl Acad Sci U S A, 93(15):7695-7700 (1996).	
	144	Molle W. et al. in J Immunol 1997, 159, 3555.	
	145	Morel, J. B. and Dangle, J.L., Cell Death Differ 1997, 4, 67 1.	
	146	Ohnishi et al., "A furin-defective cell line is able to process correctly the gp160 of human immunodeficiency virus type I", J Virol, 68(6):4075-99 (1994).	
	147	Okumura et al., "The extracellular processing of HIV-1 envelope glycoprotein gp160 by human plasmin", FEBS Lett, 442(1):39-42 (1998).	
	148	Pellegrini A, Thomas U, Franchini M, Stockli M, Klauser S, Hunziker P, von Fellenberg R. Identification of an aprotinin antiviral domain. FEBS Lett May 16, 1994;344(2-3):261-5.	
	149	Schwartz, et al., "Antiviral activity of the proteasome on incoming human immunodeficiency virus type I", J Virol, 72(5):3845-50 (1998).	
	150	Sichko ZhV, Koslova OL. Experience in treating herpetic infection with trypsin [Article in Russian]. Vrach Delo Mar. 1991;86-9.	
	151	Szeghy G, Kenyeres B. On the therapy of herpes simplex keratitis with heparin and trypsin. [Article in German] Klin Monatsbl Augenheilkd 1968; 153(6):827-30.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Complete if Known**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

10

of

17

Application Number

10/669,441

Filing Date

September 25, 2003

First Named Inventor

Leland SHAPIRO

Art Unit

1614

Examiner Name

Not Yet Assigned

Sheet	10	of	17	Attorney Docket Number	330310.00101
-------	----	----	----	------------------------	--------------

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	152	Ciliberto et al., 1985, Cell, 41:531-540.	
	153	Dery O. and Bunnett, N.W. Biochem Soc Trans 1999, 27, 246-254.	
	154	Altieri, D.C. J Leukoc Biol 1995, 58, 120-127.	
	155	Dery, O. et al. Am J Physiol 1998, 274, C1429-C1452.	
	156	Patel R. P., et al. in Biochim Biophys Acta 1999, 1411, 385-400.	
	157	Lowenstein, C. J. and Snyder, S. H. in Cell 1992, 70, 705-707.	
	158	Beck, K.F. et al. in J Exp Biol 1999, 202, 645-53.	
	159	Kirkeboen, K.A. and Strand, O.A. in Acta Anaesthesiol Scand 1999, 43, 275.	
	160	Wood, E. R. et al. in Biochem Biophys Res Commun 1993, 191, 767-74.	
	161	Lowenstein C. J. et al. in Proc. Natl. Acad. Sci. USA, 1993, 90, 9730.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.
 This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449:PTO				Complete if Known	
				Application Number	10/669,441
				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	11	of	17	Attorney Docket Number	330310.00101

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
	162	Nathan, C. in FASEB J. 1992, 6, 3501.		T ²
	163	Rehman, A. et al. in Br J Pharmacol, 1997, 122, 1702.		
	164	Pryor, W. A. et al., in Chem Biol Interact 1985, 54, 171.		
	165	Van Molle W. et al. in J Immunol 1997, 159, 3555.		
	166	Bratt, J. and Palmblad, J. in J Immunol 1997, 159, 812.		
	167	Ding, A. et al., in J. Immunol. 1990, 145, 940.		
	167	Heck, D. E. et al., in J. Biol. Chem. 1990, 267, 21277.		
	169	McCall, T.B. et al., in Biochem. Biophys. Res. Commun. 1992, 186, 680.		
	170	Punjabi, C. J. et al., in J. Immunol. 1992, 149, 2179.		
	171	Goureau, O. et al., in Proc. Natl. Acad. Sci. U.S.A. 1993, 90, 4276.		

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.
 This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449 PTO				Complete if Known	
				Application Number	10/669,441
				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	12	of	17	Attorney Docket Number	330310.00101

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	172	Schini et al. in Circ Res 1994, 74, 24.	
	173	Meki, A. R. et al. in Toxicology 1998, 36, 18519.	
	174	Popko B. and Baerwald, K. D. in Neurochem Res 1999, 24, 331.	
	175	Smith, M. E. in Neurochem Res 1999, 24, 261.	
	176	Sambrook, Fritsch & Maniatis, Molecular Cloning: A Laboratory Manual, Second Edition 1989, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, N.Y.	
	177	Remington's Pharmaceutical Sciences, 1990, p. 1519-1675, Gennaro, A.R., ed., Mack Publishing Company, Easton, PA.	
	178	Langer, R., Nature, 1998, 392, 5.	
	179	Budavari, Susan (Editor), "The Merck Index", An Encyclopedia of Chemicals, Drugs, and Biologicals; Merck & Co., Inc., 11th edition.	
	180	Merrifield, R.B., "Solid Phase Peptide Synthesis. I. The Synthesis of a Tetrapeptide", 1963, J. Am. Chem. Soc., (85):2149.	
	181	Animal Cell Culture, R.I. Freshney, ed. 1986, IRL Press, Oxford.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.
 This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449 PTO

Complete if Known

Application Number 10/669,441

Filing Date September 25, 2003

First Named Inventor Leland SHAPIRO

Art Unit 1614

Examiner Name Not Yet Assigned

Sheet

13

of

17

Attorney Docket Number

330310.00101

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	182	Scharpe et al., "Protease and their inhibitors: today and tomorrow", 1991, Biochimie, 73(1):121-126.	
	183	Kido et al., "A novel membrane-bound serine esterase in human T4+ lymphocytes immunologically reactive with antibody inhibiting syncytia induced by HIV-1. Purification and characterization", J Biol Chem., 1990, 265(35):21979-85.	
	184	Brinkman et al., "Inhibition of tryptase TL2 from human T4+ lymphocytes and inhibition of HIV-1 replication of H9 cells by recombinant aprotinin and bikunin homologues", 1997, J. Protein Chem., 16(6):651-660.	
	185	Auerswald et al., "K15R M52E) aprotinin is a weak Kunitz-type inhibitor of HIV-1 replication in H9 cells" Biomed Biochim Acta, 1991, 50(4-6):697-700.	
	186	Kamoshita et al., "Calcium requirement and inhibitor spectrum for intracellular HIV type 1 gp160 processing in cultured HeLa cells and CD4+ lymphocytes: similarity to those of viral envelope glycoprotein maturase", J Biochem. Tokyo, 1995, 117(6):1244-53.	
	187	Koito et al., "A neutralizing epitope of human immunodeficiency virus type 1 has homologous amino acid sequence with the active site of inter-alpha-trypsin inhibitor", 1989, Int Immunol, 1(6):613-8.	
	188	McNeely et al., "Secretory leukocyte protease inhibitor: a human saliva protein exhibiting anti-human immunodeficiency virus 1 activity in vitro", 1995, J Clin Invest, 96(1):456-64.	
	189	Hallenberger et al., "Inhibition of furin-mediated cleavage activation of HIV-1 glycoprotein gp160", 1992, Nature, 360(6402):358-61.	
	190	Vollenweider, et al., "Comparative cellular processing of the human immunodeficiency virus (HIV-1) envelope glycoprotein gp160 by the mammalian subtilisin/kexin-like convertases", 1996, Biochem. J.;314 (P12):521-32.	
	191	Anderson et al., "Inhibition of HIV-1 gp160-dependent membrane fusion by a furin-directed alpha 1-antitrypsin variant", 1993, J Biol Chem, 268(33):24887-91.	

Examiner Signature	Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.
 This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1985, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449: PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/669,441
				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	14	of	17	Attorney Docket Number	330310.00101

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	192	Decroly, et al., "Identification of the paired basic convertases implicated in HIV gp160 processing based on in vitro assays and expression in CD4(+) cell lines", 1996, J Biol Chem, 271(48):30442-50.	
	193	Moulard, et al., "Kex2p: a model for cellular endoprotease processing human immunodeficiency virus type 1 envelope glycoprotein precursor", Eur J Biochem, 1994, 225(2):565-72.	
	194	Avril, et al., "Identification of the U-937 membrane-associated proteinase interacting with the V3 loop of HIV-1 gp120 as cathepsin G", FEBS Lett, 1994, 345(1):81-6.	
	195	Harvima et al., "Separation and partial characterization of proteinases with substrate specificity for basic amino acids from human MOLT-4 T lymphocytes: identification of those inhibited by variable-loop-V3 peptides of HIV-1 (human immunodeficiency virus-1) envelope glycoprotein", 1993, Biochem J, 292 (Pt 3):711-8.	
	196	Bourinbaiar, et al., "Acrosin inhibitor, 4'-acetamidophenyl 4-guanidinobenzoate, an experimental vaginal contraceptive and anti-HIV activity", Contraception, 1995, 51(5):319-22.	
	197	Bristow, et al., "Inhibition of HIV-1 by modification of a host membrane protease", 1995, Int Immunol, 7(2):239-49.	
	198	Bukrinskaia et al., "Inhibition of HIV reproduction in cultured cells using proteolysis inhibitors", 1989, Vopr Virusol, 34(1):53-5.	
	199	Bourinbaiar, et al., "Effect of serine protease inhibitor, N-alpha-tosyl-L-lysyl-chloromethyl ketone (TLCK), on cell-mediated and cell-free HIV-1 spread", Cell Immunol, 1994, 155(1):230-6.	
	200	Turpin et al., "Human immunodeficiency virus type-1 (HIV-1) replication is unaffected by human secretory leukocyte protease inhibitor", 1996, Antiviral Res, 29(2-3):269-77.	
	201	Kennedy et al., "Submandibular salivary proteases: lack of a role in anti-HIV activity", 1998, J Dent Res, 77(7):1515-9.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449 PTO				Complete if Known	
				Application Number	10/669,441
				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	15	of	17	Attorney Docket Number	330310.00101

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	202	Premack, B.A. et al., "Chemokine Receptors: Gateways to Inflammation and Infection", 1996, Nature Medicine 2:1174-1178.	
	203	Zhirnov O.P. et al., "Antiviral activity of proteinase inhibitors in cultured cells infected with alpha-viruses", Mol Gen Mikrobiol Virusol, 1985, (12):30-6.	
	204	Chesnokova N.B. et al., "Antiproteases in herpetic keratitis", Metab Pediatr Syst Ophthalmol, 1986;9(1):593-6.	
	205	Adelman S.F. et al., "Protease inhibitors suppress fibrinolytic activity of herpesvirus-transformed cells", J Gen Virol, 1982, 60(Pt 1):15-24.	
	206	Chesnokova N.B. et al., "Main proteolytic inhibitors in ocular herpes", Vopr Med Khim, 1981, 27(5):663-5.	
	207	Sharpstone D. et al., "Faecal alpha 1 antitrypsin as a marker of gastrointestinal disease in HIV antibody positive individuals", Gut, 1996, 38(2):206-10.	
	208	Patel et al., "The Role of Protease Drug During Apoptosis", 1996, FASEB J, 10(5):587-597.	
	209	Estaquier J., "Fas-mediated apoptosis of CD4+ and CD8+ T cells from human immunodeficiency virus-infected persons: differential in vitro preventive effect of cytokines and protease antagonists", 1996, Blood, 15;87(12):4959-66.	
	210	Shimizu, T. et al., "DNA Fragmentation induced by Protease Activation in P53-null Human Leukemia HL60 Cells Undergoing Apoptosis Following Treatment with the Topoisomerase I Inhibitor Camptothecin: Cell-Free System Studies", 1996, Exp Cell Res, 1:226(2):292-301.	
	211	Glynn et al., "Apoptosis induced by HIV Infection in H9 T Cells is Blocked by ICE-Family Protease Inhibition but not by a FAS(CD95) Antagonist", 1996, J. Immunol, 1; 157(7):2754-2758.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete if Known	
				Application Number	10/669,441
				Filing Date	September 25, 2003
				First Named Inventor	Leland SHAPIRO
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	16	of	17	Attorney Docket Number	330310.00101

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	212	Ooka, T., et al., "Protective effects of human urinary trypsin inhibitor against trypsin-induced relaxation in rat aorta", Crit care Med, 1996, 24(11): 1903-1907.	
	213	Novradovsky, A., et al., "Endothelial Nitric Oxide Synthase as a Potential Susceptibility Gene in the Pathogenesis of Emphysema in alpha1-Antitrypsin Deficiency", 1999, Am J Respir Cell Mol Biol, 1;20(3):441-447.	
	214	Cordiali Fei et al., "Behavior of several 'progression markers' during the HIV-Ab seroconversion period. Comparison with later stages", 1992, J Biol Regul Homeost Agents, 6(2):57-64.	
	215	Lima et al., "Mucosal injury and disruption of intestinal barrier function in HIV-infected individuals with and without diarrhea and cryptosporidiosis in northeast Brazil", 1997, Am J Gastroenterol, 92(10):1861-6.	
	216	Banfi et al., "Tumor-associated trypsin inhibitor in induced and acquired immunodeficiency. Studies on transplanted and HIV-infected patients", 1991, Scand J Clin Lab Invest 51, Suppl, 207:55-8.	
	217	Deam et al., "Alpha 1-antitrypsin phenotypes in homosexual men", 1989, Pathology, 21(2):91-2.	
	218	Pezzilli et al., "Serum pancreatic enzymes in HIV-seropositive patients", Dig Dis Sci, 1992, 37(2):286-8.	
	219	Tang et al., "Inactivation of HIV-1 by trypsin and its use in demonstrating specific virus infection of cells", 1991, J Virol Methods, 33(1-2):39-46.	
	220	Glozman, "Immunologic functions of enzyme therapy of patients with orchiepididymitis", 1990, Antibiot. Khimoter, 35(7):50-52.	
	221	Franzusoff, et al., "Biochemical and genetic definition of the cellular protease required for HIV-1 gp160 processing", 1995, J Biol Chem, 270(7):3154-9.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

Complete if Known**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet	17	of	17	Attorney Docket Number	330310.00101
-------	----	----	----	------------------------	--------------

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	222	Gu et al., "Furin is important but not essential for the proteolytic maturation of gp160 of HIV-1", FEBS Lett. 1995, 365(1):95-7.	
	223	Bukrinskaia A.G., "Suppression of rotavirus SA-11 reproduction by protease inhibitors in cell culture", Vopr Virusol, 1987, 32(1):71-4.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.
 This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.